EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 June 2013
EMA/CHMP/363851/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Provenge

Autologous peripheral blood mononuclear cells activated with PAP-GM-CSF (sipuleucel-T)

On 27 June 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Provenge to Dendreon UK Ltd. This recommendation will now be forwarded to the European Commission, which will issue a legally binding decision.

The indication recommended by the CHMP is as follows: '*Provenge is indicated for the treatment of asymptomatic or minimally symptomatic metastatic (non-visceral) castrate resistant prostate cancer in male adults in whom chemotherapy is not yet clinically indicated.*' Provenge should only be administered by physicians experienced in the treatment of prostate cancer and in an environment where resuscitation equipment is available.

The active substance of Provenge consists of autologous peripheral blood mononuclear cells activated with prostatic acid phosphatase fused with granulocyte-macrophage colony-stimulating factor (sipuleucel-T). Provenge is an immunotherapy designed to induce an immune response targeted against prostatic acid phosphatase (PAP), an antigen expressed in most prostate cancers.

Provenge will be available as a dispersion for infusion (50 x 10^6 $CD54^+$ cells/250 mL). The recommended course of treatment is 3 doses at approximately 2-week intervals. Each dose of Provenge is preceded by a standard leukapheresis procedure approximately 3 days prior to the scheduled infusion date.

The CHMP decided that the benefits of Provenge are greater than its risks following an assessment of data, including one main study that demonstrated improved survival of patients when compared with placebo. In general Provenge is well tolerated. The most common side effects are chills, fatigue, pyrexia, nausea, arthralgia, headache and vomiting.

A pharmacovigilance plan for Provenge will be implemented as part of the marketing authorisation.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7<sector fax>
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.